

HOUSTON **CELIAC-SPRUE** SUPPORT GROUP

Janet Y. Rinehart, Chairman
11011 Chevy Chase
Houston, TX 77042-2606

713/783-7608

E-mail: txjanet@swbell.net
Celiacs Helping Celiacs

Chapter #25 of CSA/USA, Inc. 99 APR -6 110 06

March 26, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: FDA-Docket No. 98 N-1265

To whom it may concern:

I have **Celiac** Disease, a non-contagious auto-immune condition that causes me to become ill if I eat anything containing or derived from wheat, oats, barley, rye or malt.

Many over the counter and prescription medications contain ingredients which are harmful to me, including excipients, such as stabilizers, preservatives, colorings, flavorings, sweeteners, binders, **dilutants, disintegrants**, lubricants, coatings, additives and inert agents. If I need an over the counter or prescription medication, I must do extensive research to see if it contains anything harmful to me. Many times there isn't a product available commercially, and so I have to have a product custom made. Stokes Pharmacy, in New Jersey, is one **place** where I can get a custom replacement for a product that would otherwise be harmful to me.

If the subject restriction were implemented, then a safe source of both over the counter and prescription medications will be denied to me. More important these sources will be denied to the thousands of other people who have dietary restrictions and allergies.

Sincerely,

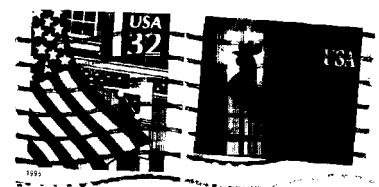
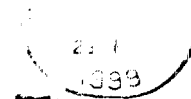

Janet Y. Rinehart

Past President, CSA/USA, Inc.

98N-1265

C 843

Janet Y. Rinehart
11011 Chevy Chase
Houston, TX 77042-2606



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

20857/0003

